



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0132; FRL-9411-11-OCSPP]

Certain New Chemicals; Receipt and Status Information for November 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the *Federal Register* pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 11/1/2022 to 11/30/2022.

DATES: Comments identified by the specific case number provided in this document must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2022-0132, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Project Management and Operations Division (MC 7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: *rahai.jim@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 11/01/2022 to 11/30/2022. The Agency is providing notice of receipt of PMNs, SNUNs, and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an "existing" chemical substance or a "new" chemical substance. Any

chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a "new chemical substance," while a chemical substance that is listed on the TSCA Inventory is classified as an "existing chemical substance." (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: <https://www.epa.gov/tscainventory>.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN, or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for "test marketing" purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: <https://www.epa.gov/chemicals-under-tsca>.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the *Federal Register* certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the *Federal Register* after providing notice of such changes to the public and an opportunity to comment (see the *Federal Register* of May 12, 1995 (60 FR 25798) (FRL-4942-7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received,

the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.*, domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (*e.g.* P-18-1234A). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future version of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Approved* from 11/1/2022 to 11/30/2022

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-23-0002	1	10/07/2022	CBI	(G) Manufacture of a recombinant	(G) Microorganism stably transformed to express a recombinant protein

				protein	
P-20-0060A	9	11/05/2022	CBI	(S) Catalyst for polyurethane foam manufacturing	(G) Bismuth Carboxylate complexes
P-22-0019A	2	11/23/2022	CBI	(G) Film-forming polymer	(G) Protein sodium complexes, polymers with aromatic acid chloride, ethylene diamine and amino acid
P-22-0044A	3	11/22/2022	CBI	(G) Site Limited Intermediate	(G) Silica gel, reaction products with alkyl metal salt
P-22-0107A	3	11/29/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-22-0108A	3	11/29/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-22-0109A	3	11/29/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-22-0110A	3	11/29/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-22-0111A	3	11/29/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial applications	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-22-	3	11/29/2022	Locus	(G)	(G) Glycolipids,

0112A			Fermentation Solutions	Surfactant for consumer, industrial, commercial applications	sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts
P-23-0006A	3	11/04/2022	Siltech, Inc.	(G) Additive	(S) Siloxanes and silicones, di-Me, Me hydrogen, polymers with vinyl group-terminated di-Me siloxanes
P-23-0014	4	11/21/2022	CBI	(S) Intermediate in production of fragrance	(G) [Polyalkyl-methylenepolyhydro-polycyclic]alkyl acetate
P-23-0017	2	11/07/2022	Givaudan Fragrances Corp.	(S) Encapsulant for time-released delivery of fragrance	(G) Hydrolyzed collagen, polymer with aromatic isocyanate, N-triethoxysilyl-alkanamine, pectic polysaccharide and poly alkyl alcohol
P-23-0018	2	11/02/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) Vegetable oil, polymer with pimelin ketone, oxymethylene and polymethylenepolyphe nylene isocyanate
P-23-0018A	3	11/14/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) Vegetable oil, polymer with pimelin ketone, oxymethylene and polymethylenepolyphe nylene isocyanate
P-23-0019	2	11/04/2022	CBI	(G) Photolithogra phy	(G) Sulfonium, triphenyl-, polyhydro-5-(polyfluoro-2-sulfoalkyl)spiro[4,7-methano-1,3-benzodioxole-2,2'-polycycloalkane]-5-carboxylate (1:1)
P-23-0020	1	11/04/2022	Siltech, Inc.	(G) Additive / intermediate	(S) Silsesquioxanes, 3-mercaptopropyl, polymers with silic acid (H4SiO4) tetra-Et ester, [(trimethylsilyl)oxy]-terminated
P-23-0021	2	11/16/2022	CBI	(G) Resin used for the	(G) Ethylene, polymer with

				fabrication of articles	tetrafluoroethylene and hexafluoropropene
P-23-0022	1	11/11/2022	Cabot Corporation	(G) Additive used in industrial applications	(G) Multi-walled carbon nanotubes
P-23-0023	1	11/11/2022	Cabot Corporation	(G) Additive used in industrial applications.	(G) Multi-walled carbon nanotubes
P-23-0024	1	11/11/2022	Cabot Corporation	(G) Additive used in industrial applications.	(G) Multi-walled carbon nanotubes
P-23-0025	1	11/11/2022	Solugen, Inc.	(G) Additive used in consumer, industrial, and commercial applications	(G) Polycarboxylic acid, salt
P-23-0026	1	11/11/2022	Solugen, Inc.	(G) Additive used in consumer, industrial, and commercial applications	(G) Polycarboxylic acid, salt
P-23-0027	1	11/11/2022	Solugen, Inc.	(G) Additive used in consumer, industrial, and commercial applications	(G) Polycarboxylic acid, salt
P-23-0029	1	11/14/2022	CBI	(G) Battery Cathode Manufacturing	(G) Cobalt metal nickel oxide
P-23-0030	1	11/17/2022	CBI	(G) A polymer of insulating materials	(G) Phenol, polyalkylcarbo bis-, polymer with 2-carbomonocyclichalohe teromonocycle, bis[(alkenylcarbomono cyclic)alkyl] ether
P-23-0031	1	11/21/2022	Tetramer Technologies, LLC	(G) Component in Lubricants	(G) Glycerin, polyalkoxylated, mixed fatty acid and alkyl diacid esters
P-23-	2	11/28/2022	ADC - Adrian	(S) Industrial	(S) 1,3 propanediol,

0032				<p>belting - Tough material with very good flex fatigue properties to replace current products.</p> <p>No crush wheels - used in multiple industries; the good flex fatigue properties, resilience, and toughness would make an ideal polymer for this application.</p> <p>General replacement for polytetramethylene ether glycol (PTMEG)-based cast urethane parts fatigue properties.</p>	polymer with 1,3 diisocyanatomethylbenzene
P-23-0033	1	11/22/2022	Cabot Corporation	(G) Additive used in industrial applications	(G) Multi-walled carbon nanotubes
P-23-0034	1	11/23/2022	CBI	(G) Process aid	(G) Derivative of a diallyldimethylammonium chloride and substituted ethylene copolymer
SN-22-0007A	4	11/11/2022	Braven Environmental, LLC	(G) Product of Pyrolysis manufacturing	(S) Waste plastics, pyrolyzed, C5-12 fraction
SN-22-	4	11/11/2022	Braven	(G) Product	(S) Waste plastics,

0008A			Environmental, LLC	of Pyrolysis Manufacturing	pyrolyzed, C20-55 fraction
SN-22-0009A	4	11/11/2022	Braven Environmental, LLC	(G) Product of Pyrolysis Manufacturing	(S) Waste plastics, pyrolyzed, C9-20 fraction
SN-23-0001	2	11/03/2022	Ultium Cells, LLC	(S) Use as a conductive material in battery cells.	(G) Single-walled carbon nanotubes

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.*, amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

Table II. – NOCs Approved* from 11/1/2022 to 11/30/2022

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
P-17-0306A	11/22/2022	09/11/2022	Amended generic chemical name	(G) Vegetable oil, polymer with alkyl dialcohol, cyclic dicarboxylic anhydride, aromatic dicarboxylic acid, and polyglycol
P-18-0362	11/03/2022	10/20/2022	N	(S) 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 2, 4-diisocyanato-1-methylbenzene, alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)] and alpha, alpha prime, alpha double prime-1,2, 3-propanetriyltris[omega-hydroxypoly[oxy(methyl-1,3-ethandiyl)]], me et ketone oxime blocked
P-19-0019A	11/16/2022	08/21/2021	Amended generic chemical name	(G) Chlorofluoroalkane
P-19-	11/11/2022	11/11/2022	N	(S) Benzoic acid, 2-chloro-4-

0108				methyl-, ethyl ester
P-19-0187	11/11/2022	11/11/2022	N	(S) Benzoic acid, 2-chloro-4-methyl-, sodium salt (1:1)

*The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table III. – Test Information Received from 11/1/2022 to 11/30/2022

Case No.	Received Date	Type of Test Information	Chemical Substance
P-13-0021	11/15/2022	Test Data Validation Study	(G) Perfluoroacrylate polymer
P-16-0543	11/28/2022	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt
P-16-0543	11/14/2022	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 13, 2022.

Pamela Myrick,

Director, Project Management and Operations Division,

Office of Pollution Prevention and Toxics.

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